

REMARKS/ARGUMENTS

Claims 1-23 are pending in the application. Claims 1-11 have been withdrawn without prejudice, in favor of claims 12-23. Claims 24-38 have been added by this amendment.

Each of claims 1-23 stand rejected under the prior art of record. Claims 1, 4, and 8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Warner (4,903,695). Claims 1-3, 5-7, 11-19, 22, and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Warner in view of Bille (4,907,586). Claims 9, 10, 20, and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Warner and Bille in view of Bronstein (4,842,599). Finally, Claims 1-5, 8, and 10 are rejected under obviousness-type double patenting as being unpatentable over Claims 1, 2, 4, 5, 7, 8, 10-13, and 15 of Juhasz (6,110,166) in view of Warner, and Claims 6, 7, 9, and 11-23 are rejected under obviousness-type double patenting as being unpatentable over Claims 3, 6, 9, and 14 of Juhasz in view of Bronstein. Applicant respectfully traverses each of the Examiner's rejections.

I. 102(b) – Claims 1, 4, and 8

These claims have been withdrawn in favor of new claims 24-37.

II. 103(a) - Claims 1-3, 5-7, 11-19, 22, and 23

A. Warner and Bille

The Warner reference is directed to a method and apparatus for performing ophthalmic surgery on the cornea to correct optical deficiencies of an eye. Col. 1, lns. 7-9. Warner discloses using a blade to create a “lenticle” which is then removed so that the exposed stromal tissue can be exposed to a laser beam. In contrast to the subject matter of the claimed invention, Warner only discloses using a blade, or microkeratome, to create the “lenticle” which is then removed. The claimed invention discloses the use of a pulsed laser beam to create a removable layer of corneal tissue.

Further, the Bille reference does not cure the deficiencies of the Warner reference. Bille discloses the use of a laser to modify corneal tissue without creating any removable and replaceable portion of corneal tissue. Bille teaches using a laser to create a substantially vertical incision from the surface of the cornea to a predesired depth to reshape the cornea. (See Figure 4.) Additionally, Bille teaches using a laser for “internal ablation *i.e.* the ablation of tissue which is wholly nonsuperficial and unexposed” (col. 10, lns. 31-33) and for surface ablation (*see e.g.*, col. 3, lns. 55-56). It would not have been obvious to one of skill in the art to use the laser disclosed in Bille to perform the focusing and moving steps of the method of reshaping the cornea of the eye described in claim 12.

Claim 12, as amended, recites a method for reshaping the cornea of an eye which comprises the steps of focusing the rays of a pulsed laser beam within the stroma of the cornea to photoalter stromal tissue, moving said focal point of the laser beam along a predetermined path within the stroma of the cornea to photoalter a layer of stromal tissue, incising the cornea between the anterior surface of the cornea and the layer to create a peripheral edge for a removable corneal layer, lifting said removable corneal layer, photoaltering at least a portion of the bed of stromal tissue, and replacing the removable corneal layer.

To establish *prima facie* obviousness, the Examiner must establish that all claim limitations are taught or suggested by the prior art. *In re Roy*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). For example, the creation of a removable corneal layer is not taught, or suggested, by the combination of Bille and Warner. Thus, even if the Bille and Warner references could be properly combined, the resulting combination does not establish obviousness because the combination does not include all of the elements discussed above (recited in amended claim 12).

Even if all elements of claim 12 were available from the Bille and Warner references, there is no teaching in the cited references, or from the general knowledge available to one of ordinary skill in the art, which would allow the teachings of these two references to be combined so as to produce a workable method according to the claimed invention. As discussed above, among other things, Bille does not disclose any removable and replaceable corneal layer, but instead teaches using a laser to create a substantially vertical incision, to create a wholly nonsuperficial unexposed ablated portion of corneal tissue, or to surface

ablate tissue. Furthermore, Warner discloses using a microkeratome to create a "lenticle." How such different concepts could be combined is beyond the teachings of these references.

Such a combination of prior art teachings cannot be shown to establish obviousness absent some teaching, incentive, or suggestion in the prior art. *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 2221 U.S.P.Q. 929, 933 (Fed. Cir. 1984); *In Re Fine*, 837 F.2d 1071, 35 U.S.P.Q. 1596 (Fed. Cir. 1988).

Furthermore, it is known in the art that the creation of the removable corneal layer with a pulsed laser beam differs significantly from the creation of a "lenticle" with a blade. The pulsed laser beam separates corneal lamellae in the stroma, whereas the blade slices through the lamellae. Additionally, tissue that may not have been affected by the laser connects the removable corneal layer to the underlying stromal bed, and is only completely separated when the surgeon lifts the removable corneal layer from the stromal bed.

Additionally, using a pulsed laser beam to create a removable corneal layer is considered to be safer than using a microkeratome. If the surgeon starts the pulsed laser beam procedure and creates bubbles of photodisrupted tissue, and the patient moves or other movement takes place, the surgeon can wait for a short period of time, and then start the procedure again. Such is not the case with complications with a microkeratome. While infrequent, if a microkeratome jams or loses suction on the eye, "buttonhole" flaps, partial resections, and/or corneal abrasions that can cause scarring across the visual axis can result. In the case of the partial resection, for example, the surgery must be aborted, and cannot be re-attempted for 3-4 months.

Moreover, the method of the present invention creates the removable corneal layer under very low vacuum, delivering the laser energy directly to the stromal layer of the cornea through a disposable glass lens. The outer surface of the cornea suffers no trauma, and the procedure is completely painless. In contrast, the microkeratome uses a higher level of vacuum to applanate the cornea through a suction ring and hold it tightly as the metal blade slices across to create a removable corneal layer. In testing, greater flap stability as well as a high degree of accuracy in both the depth and size of the resections have been demonstrated with the use of the laser to create the removable corneal layer.

Accordingly, the combination of Bille and Warner does not provide a proper basis for a rejection under 35 U.S.C. § 103(a). Withdrawal of the Examiner's rejection of claim 12 under 35 U.S.C. § 103(a) is respectfully requested.

Each of claims 13-19, 22, and 23 depends from claim 12 and is, therefore, allowable for reasons as set forth above with respect to claim 12. Additionally, each of these claims contains additional patentable subject matter.

Amended claim 13 recites that the photoaltered portion created by the photoablation is lens-shaped. Neither Warner nor Bille address this subject matter. Thus, claim 13 contains additional patentable subject matter.

Claims 14-16 recite that the anterior and posterior surfaces are either concave or convex-shaped. The microkeratome of Warner is incapable of performing this result; a blade can only make a planar cut, and cannot make a concave or convex-shaped cut. Thus, claims 14-16 each contain additional patentable subject matter.

Claims 17 and 18 are directed to the shape of the boundary of the bed of stromal tissue. Claim 17 prescribes a substantially circular border, while claim 18 prescribes a substantially oval-shaped border. Again, the mechanics of using a microkeratome eliminate the possibility of creating an oval-shaped bed of stromal tissue by cutting a portion of the substantially spherical eyeball; thus the Warner reference is incapable of producing this result. Neither Warner nor Bille teach these limitations, nor do they teach the use of a laser to create internal surfaces in a circular shape. Thus, claims 17 and 18 each contain additional patentable subject matter.

Claim 19 is directed to using an excimer laser to perform the photoaltering step of claim 12, while claims 22 and 23 are directed to using a pulsed infrared laser and a visible pulsed laser, respectively. Warner discloses the use of an excimer laser, but only after creating a "lenticle" with a microkeratome. Warner does not teach creating a removable corneal layer with a laser of any kind. Thus, using these lasers in combination with the creation of a removable corneal layer created with a laser would not be obvious in light of the cited references. Thus, claims 19, 22, and 23 each contain additional patentable subject matter.

III. Warner, Bille, and Bronstein - Claims 9, 10, 20, and 21

Claim 20 recites a corneal flap with a peripheral edge formed with a tab to assist in lifting and repositioning of the flap. Claim 21 recites a corneal flap with a peripheral edge formed with an interlocking feature to hold the flap in place after the repositioning of the flap. Claims 20 and 21 depend from claim 12. These claims require a combination of requirements which is neither taught nor suggested by the cited references. Specifically, claims 20 and 21 require, in combination, (a) the creation of a removable corneal layer with a pulsed laser beam (b) which has an interlocking feature or tab that subsequently stabilizes the flap on the cornea. As discussed above, Warner teaches the use of a microtome, or microkeratome, to create a "lenticle", while Bille teaches using a laser to create a substantially vertical incision, or to create a wholly nonsuperficial unexposed ablated portion of corneal tissue. Bronstein is concerned with a prosthetic device, not a corneal layer (which is inherently living tissue).

Accordingly, the combination of Warner, Bille, and Bronstein does not provide a proper basis for a rejection under 35 U.S.C. § 103(a). Withdrawal of the Examiner's rejection of claims 20 and 21 under 35 U.S.C. § 103(a) is respectfully requested.

IV. Obviousness-type Double Patenting

Claims 1-5, 8, and 10 are rejected under obviousness-type double patenting as being unpatentable over Claims 1, 2, 4, 5, 7, 8, 10-13, and 15 of Juhasz (6,110,166) in view of Warner, and Claims 6, 7, 9, and 11-23 are rejected under obviousness-type double patenting as being unpatentable over Claims 3, 6, 9, and 14 of Juhasz in view of Bronstein. Applicants have enclosed a terminal disclaimer to overcome this rejection. Applicants note that the filing of a terminal disclaimer creates no estoppel as to the obviousness or nonobviousness of claims. *Quad Environmental Tech. Corp. v. Union Sanitary Dist.*, 946 F.2d 870 (Fed. Cir. 1991).

V. New Claims 24-36

New claims 24-36 are based on the original specification filed on March 20, 1995 (Application No. 08/407,508) and contain patentable subject matter. These claims are directed to a method for accessing internal corneal tissue by using a laser, and contain some limitations similar to the ones discussed previously with respect to the amended claims, and are believed to be patentable for the same reasons discussed above.

VI. Conclusion

Attached hereto is a version of the pending claims after the current amendment. The attached page is captioned "**Version with currently pending claims.**"

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

The Commissioner is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 06-2375, under Order No. HO-P02276US1. A duplicate copy of this paper is enclosed. If a Petition is required for proper submission of this Response, Applicant hereby provides said Petition and authorization of any filing or petitioner fee.

The undersigned is available for consultation if the Examiner believes such consultation will help resolve any outstanding issue or otherwise expedite the prosecution of this application.

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Respectfully submitted,

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Version With Currently Pending Claims

What is claimed is:

12. (Amended) A method for reshaping the cornea of an eye, said method comprising the steps of:
- focusing a pulsed laser beam within the stroma of the cornea to photoalter stromal tissue at a focal point;
 - moving said focal point of said pulsed laser beam along a predetermined path within the stroma of the cornea to photoalter a layer of stromal tissue, said layer being an interface between the interior surface of a removable corneal layer and a bed of stromal tissue;
 - incising the cornea between the anterior surface of the cornea and the layer to create a peripheral edge for said removable corneal layer, said removable corneal layer substantially overlying said bed of stromal tissue;
 - lifting said removable corneal layer to expose said bed of stromal tissue;
 - photoaltering at least a portion of said bed of stromal tissue; and
 - replacing said removable corneal layer over said photoaltered bed of stromal tissue.
13. A method as recited in claim 12 wherein said photoaltered portion is lens-shaped having an anterior surface, a posterior surface and an annular surface.
14. A method as recited in claim 13 wherein said anterior surface is concave shape.
15. A method as recited in claim 13 wherein said posterior surface is convex shape.
16. A method as recited in claim 13 wherein said anterior surface is convex shape.
17. A method as recited in claim 12 wherein said bed of stromal tissue has a boundary and said boundary is substantially in the shape of a circle.
18. A method as recited in claim 12 wherein said bed of stromal tissue has a boundary and said boundary is substantially in the shape of an oval.

19. A method as recited in claim 12 wherein said photoaltering step is accomplished using an excimer laser.

20. The method of claim 38 wherein said peripheral edge of said flap is formed with a tab to assist in lifting and repositioning of said flap.

21. The method of claim 38 wherein said peripheral edge of said flap is formed with an interlocking feature to hold said flap in place after said repositioning step.

22. A method as recited in claim 12 wherein said photoaltering step is accomplished using a pulsed infrared laser.

23. A method as recited in claim 12 wherein said photoaltering step is accomplished using a visible pulsed laser.

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24. A method for accessing internal corneal tissue with a laser, said method comprising the steps of:

defining an anterior internal surface having a first periphery and a posterior internal surface having a second periphery in the stroma by directing the focal point of a laser beam along a first predetermined path to photodisrupt overlapping areas of stromal tissue; and

defining an access to the anterior internal surface and the posterior internal surface by directing the focal point of a laser beam along a second predetermined path to photodisrupt overlapping areas of stromal tissue, said predetermined path extending from the first and second peripheries to the outer surface of the cornea.

25. The method of claim 24, wherein the step of defining the anterior internal surface and the posterior internal surface includes the step of forming the first predetermined path in the pattern of a spiral.

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26. (New) The method of claim 24, wherein the step of defining the anterior internal surface and the posterior internal surface includes the steps of forming a first path to define the anterior surface and a second path to define the posterior surface.

27. (New) The method of claim 24, wherein the anterior internal surface and the posterior internal surface coincide.

28. (New) The method of claim 27, wherein the first periphery and the second periphery coincide.

29. (New) The method of claim 26, and further including the steps of forming the anterior internal surface in a convex shape and, forming the posterior internal surface in a concave shape, such that a lens-shaped body of stromal tissue is formed between the two surfaces.

A2 30. (New) The method of claim 29, and further including the step of removing the lens-shaped body through an opening formed along the second predetermined path.

31. (New) The method of claim 24, and further including the step of forming the second predetermined path in a spiral pattern starting at the first and second peripheries and extending to the outer surface of the cornea.

32. (New) The method of claim 24, and further including the step of forming the anterior internal surface in a concave shape.

33. (New) The method of claim 24, and further including the step of forming the posterior internal surface in a concave shape.

34. (New) The method of claim 24, and further including the step of forming the anterior internal surface in a convex shape.

35. (New) The method of claim 24, and further including the step of forming the posterior internal surface in a convex shape.

36. (New) The method of claim 24, and further including the step of forming the anterior internal surface and the posterior internal surface substantially in the shape of a circle.

37. (New) The method of claim 24, and further including the step of forming the anterior internal surface and the posterior internal surface substantially in the shape of an oval.

38. (New) The method of claim 12 wherein said removable layer remains attached to the cornea at a hinge, creating a flap with a peripheral edge.